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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,564

10/15/2004

Rajendra K Joshi

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

04/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,564	Applicant(s) JOSHI ET AL.	
	Examiner YEVEGENY VALENROD	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 20-26 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 20-22, 24-26, 31-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 23, 25, 30, 34, 36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/08 has been entered.

Rejection of claims 5, 7-15, 20-37 under 35 USC 112 first paragraph is withdrawn in view of applicants' amendments.

Rejection of claims 5, 7, 9, 13 and 14 under 35 USC 102(b) made over Kitchens et al. is withdrawn in view of applicants' amendments.

Rejection of claims 5, 7, 9-12 and 15 under 35 USC 102(b) made over Farina et al. is withdrawn in view of applicants' amendments.

Rejection of claims 5, 7 and 8 under 35 USC 102(b) made over Doerhoefer et al is withdrawn in view of applicants' amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 recites the limitation "R₁ is hydrogen" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 20 does not provide for R₁ being hydrogen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 13, 14, 21, 22 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitchens et al. (US 5,042,986). Kitchens et al disclose a composition comprising trans-1,2,3,4-cyclobutane tetracarboxylic acid in water (column 3-4 first 5 lines of Example 1). Water is an acceptable pharmaceutical excipient.

Claims 20-22, 25, 26 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt-Dunker et al. (US 3,920,837). In Example 4 in column 6, Schmidt-Dunker et al. teach preparation of a capsule and tablet forms of pharmaceutical compositions comprising cyclohexane-1,2,3,4,5,6-hexacarboxylic acid.

Claim Rejections - 35 USC § 103

Art Unit: 1621

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 15, 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt-Dunker et al. (US 3,920,837).

Scope of prior art

In Example 4 in column 6, Schmidt-Dunker et al. teach preparation of a capsule and tablet forms of pharmaceutical compositions comprising cyclohexane-1,2,3,4,5,6-hexacarboxylic acid.

Ascertaining the difference between prior art and instant claims

Schmidt-Dunker et al. differ from the instant claims in the following way:

1) Claims 13 and 15 require trans stereochemistry, Schmidt-Dunker et al. do not disclose the stereochemistry of their polycarboxylic acid.

2) Claims 24 and 32 require an enteric coating for the oral dosage form.

Although Schmidt-Dunker et al. teach capsules and tablets, they fail to disclose the type of coating used.

3) Claim 33 requires a powder to be put into a capsule, Schmidt-Dunker et al. fail to disclose in which form the polycarboxylic acid is prepared into a capsule.

Obviousness

1) Stereochemistry. First, Although Schmidt-Dunker et al. do not disclose which stereoisomer is utilized in their pharmaceutical formulations; the trans isomer claimed

Art Unit: 1621

by the applicant is the most stable one and a solution and its reasonable to presume that the trans is the isomer present. Second, without unexpected results arising from stereochemical considerations stereoisomers are obvious. In order to patent an optical isomer, it is necessary to show that they possess "...qualities [which] are utterly unobtainable" in the racemic mixture. Sterling Drug v. Watson, 108 USPQ 37. Note also, Pfizer v Int. Rectifier Corp., 190 USPQ 273, 280; Lilly v. Generex, 174 USPQ 65. See also In re Volweiler, 146 USPQ 137 (requiring that the claimed component of an old mixture "be so different in properties and uses as to be in effect a new compound"). A mere improvement in properties does not necessarily suffice. In re Weijland, 69 USPQ 449; Ex parte Hald, Paper 15 in U.S. Patent No. 2,647,145; Ex parte Cavallito, 89 USPQ 449. The reference does not have to suggest resolution of the racemate. One of ordinary skill in the art is presumed to be able to do so. The expectation with regard to enantiomers is that activities as the pertain to living systems are expected to be different. In re Adamson, 272 F.2d 952, 125 USPQ 233 (CCPA 1960).

2) One of ordinary skill in the art would be motivated to choose from a limited number of coating available for coating the tablet including enteric coating. Coating and their physiological stability/effect are well known to those skilled in the art and applying a particular type of a known coating produces expected results.

3) Powder in a capsule. One skilled in the art would have found it obvious to attempt various delivery methods for the invention of Schmidt-Dunker et al. Providing powders in a capsule is a well known method to those skilled in the arts and does not render the invention patentable absent unexpected results.

Claim objections

Claims 23, 25, 30, 34, 36 and 37 are objected to for being dependent on a rejected claim.

Conclusion

Claims 13-15, 20-26, 30-37 are pending.

Claims 13-15, 20-22, 24-26, 31-33 and 35 are rejected.

Claims 23, 25, 30, 34, 36 and 37 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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